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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,259	03/18/2004	Ralph B. Lilly	Anon-001:C	5397

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,259	LILLY ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 11/17/08. Claims 1 and 22-24 have been amended. Claims 1-4, 6-10, and 22-24 remain pending.

Specification

2. The amendment filed 11/17/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The newly added recitation of "general purpose computer" and "electronic" patterns within claims 1 and 22-24 appears to constitute new matter.

In particular, Applicant does not point to, nor was the Examiner able to find support for this newly added language within the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Claims 1 and 22-24 recite limitations that are new matter, as discussed above, and are therefore rejected.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in the 11/17/08 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 2-4 above in the next communication sent in response to the present Office Action.

6. Claims 1-4 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1).
(A) Referring to claim 1, Cunningham discloses a method for tracking prescriptive medication, to address and control prescription drug abuse, said method comprising (abstract of Cunningham):

providing respective computer connections to a plurality of entities, said plurality of entities comprising a plurality of affiliated pharmacies (Fig. 1 and col. 4, lines 37-62 of Cunningham);

storing pharmaceutical data in a general purpose computer related to prescriptive medication purchases obtained by a plurality of prescriptive medication purchasers from said plurality of affiliated pharmacies (col. 2, line 64 – col. 3, line 10 and col. 3, lines 54-67 of Cunningham; the Examiner interprets "patients" to be a form of "prescriptive medication purchasers"); and

selectively transferring said pharmaceutical computer data through said computer connections to at least one of said plurality of entities for obtaining a prescriptive history of a selected prescriptive medication purchaser for medications purchased by said selected prescriptive medication purchaser from all of said plurality of affiliated pharmacies based on said transferred pharmaceutical computer data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham); and

generating from said prescriptive history of said selected purchaser one or more electronic patterns which flag prescriptive drug abuse (col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose unaffiliated pharmacies and that the prescriptive history contains all prescriptive medications purchased in the aggregate.

Borsand discloses medication history that includes medication prescribed by other providers (para. 10, para. 11, and para. 56 of Borsand).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Borsand within Cunningham. The motivation for doing so would have been to maximize the probability that pharmaceutical interactions and allergic reactions would be detected before a prescription is issued (para. 56 of Borsand).

(B) Referring to claim 2, Cunningham discloses providing that said at least one of said plurality of entities comprises a physician's office and said selected prescriptive medication purchaser is a patient of said physician (col. 2, lines 40-44 and col. 6, lines 44-61 of Cunningham); and

said prescriber utilizing said pharmaceutical computer data (Fig. 1 of Cunningham).

Cunningham does not expressly disclose that the physician's office verifies said prescriptive history of said selected prescriptive medication purchaser.

Borsand discloses the physician verifying said prescriptive history of said selected prescriptive medication purchaser (para. 56 of Borsand).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Borsand within Cunningham. The motivation for doing so would have been to maximize the probability that pharmaceutical interactions and allergic reactions would be detected before a prescription is issued (para. 56 of Borsand).

(C) Referring to claim 3, Cunningham discloses providing that said at least one of said plurality of entities comprises a pharmacy with a pharmacist (col. 11, lines 38-40 of Cunningham);

said selected prescriptive medication purchaser requesting that said pharmacist fill a new prescriptive medication (col. 3, lines 54-57 of Cunningham); and

said pharmacist utilizing said pharmaceutical computer data to compare said new prescriptive medication with respect to said prescriptive history of said selected prescriptive medication purchaser (col. 3, lines 54-67 of Cunningham).

(D) Referring to claim 4, Cunningham discloses said pharmacist accepting or declining to fill said new prescriptive medication based on said prescriptive history (col. 3, lines 54-67 of Cunningham).

(E) Referring to claim 6, Cunningham does not expressly disclose providing that at least one of said plurality of entities comprises a hospital and said selected prescriptive medication purchaser is a patient of said hospital; and said hospital utilizing said

pharmaceutical computer data to determine said prescriptive history of said selected prescriptive medication purchaser.

Borsand discloses providing that at least one of said plurality of entities comprises a hospital and said selected prescriptive medication purchaser is a patient of said hospital (para. 31 of Borsand); and said hospital utilizing said pharmaceutical computer data to determine said prescriptive history of said selected prescriptive medication purchaser (para. 56 of Borsand).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a hospital within the system of Cunningham. The motivation for doing so would have been to include a variety of different settings that are used in treating patients (para. 31 of Borsand).

7. Claims 7-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1), and further in view of Munoz et al. (US 2002/0052760 A1).

(A) Referring to claim 7, Cunningham discloses providing that said pharmaceutical computer data for each of said prescriptive medication purchases comprises a name of a respective prescriptive medication purchaser, a drug prescribed, said respective prescriptive medication purchaser, a quantity of said drug, a dosage of said drug, a

pharmacist name, and a doctor name (col. 5, lines 16-60 and col. 6, lines 6-25 of Cunningham).

Cunningham and Borsand do not disclose an address of said respective prescriptive medication purchaser.

Munoz discloses an address of a respective prescriptive medication purchaser (para. 49 of Munoz).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Munoz within Cunningham and Borsand. The motivation for doing so would have been to indicate where to send the delivery (para. 49 of Munoz).

(B) Referring to claim 8, Cunningham and Borsand do not disclose searching said stored pharmaceutical computer data based on one or more of said name of a respective prescriptive medication purchaser, said address of said respective prescriptive medication purchaser, said drug prescribed, said respective prescriptive medication purchaser, said quantity of said drug, said dosage of said drug, said pharmacist name, and said doctor name.

Munoz discloses searching said stored pharmaceutical computer data based on said drug prescribed (para. 41 of Munoz).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Munoz within Cunningham and

Borsand. The motivation for doing so would have been to find records that meet the desired characteristics (para. 41 of Munoz).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other elements are also disclosed.

(C) Referring to claim 9, Cunningham discloses storing pharmaceutical data related to whether a request for filling a prescriptive medication is filled or declined (col. 3, lines 54-67 of Cunningham).

(D) Referring to claim 10, Cunningham discloses providing that at least one of said plurality of entities comprises a government agency (col. 2, lines 54-59 of Cunningham).

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1), in view of Rice et al. (US 2002/0042723 A1).

(A) Referring to claim 22, Cunningham discloses a method for tracking prescriptive medications, to address and control prescription drug abuse, said method comprising (abstract of Cunningham);

providing respective computer connections to a plurality of entities (Fig. 1, col. 4, lines 37-62, and abstract of Cunningham);

storing pharmaceutical data in a general purpose computer relating to prescriptive medication purchases obtained by a plurality of prescriptive medication purchasers from a plurality of pharmacies (col. 2, line 64 – col. 3, line 10 and col. 3,

lines 54-67 of Cunningham; the Examiner interprets "patients" to be a form of "prescriptive medication purchasers");

selectively transferring said pharmaceutical computer data through said computer connections to at least one of said plurality of entities for obtaining a prescriptive history of a selected prescriptive medication purchaser for all prescriptive medications purchased in the aggregate by said selected prescriptive medication purchaser from all of said plurality of pharmacies based on said transferred pharmaceutical computer data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham); and

generating from said prescription history of said selected purchaser one or more electronic patterns which flag prescriptive drug abuse (col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose said plurality of entities being a group consisting essentially of a plurality of hospitals, a plurality of doctors, and at least one government agency, or combinations thereof.

Rice discloses said plurality of entities being a group consisting essentially of a plurality of hospitals, a plurality of doctors, and at least one government agency, or combinations thereof (see Fig. 1 and abstract of Rice).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Rice within Cunningham. The motivation for doing so would have been to facilitate the retrieval and delivery of

information and alerts to a plurality of sources/consumers (para. 13 and para. 18 of Rice).

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1), in view of Rice et al. (US 2002/0042723 A1), and further in view of Edelson et al. (5,737,539).

(A) Referring to claim 23, Cunningham and Rice do not disclose wherein the one or more electronic patterns from the prescriptive history indicate prescription duplication, or multi-source prescription abuse.

Edelson discloses wherein the one or more electronic patterns from the prescriptive history indicate prescription duplication, or multi-source prescription abuse (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham and Rice. The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1), and further in view of Edelson et al. (5,737,539).

(A) Referring to claim 24, Cunningham and Borsand do not disclose Cunningham does not disclose wherein the one or more electronic patterns from the prescriptive history indicate prescription duplication, or multi-source prescription abuse.

Edelson discloses wherein the one or more electronic patterns from the prescriptive history indicate prescription duplication, or multi-source prescription abuse (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham and Borsand. The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

Response to Arguments

11. Applicant's arguments filed 11/17/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 11/17/08.

(1) Applicant argues that the Cunningham patent is nothing more than keeping track of the number of refills that have been obtained as compared to the number of refills which remain to be filled. This is totally distinct from a system according to the present invention, which as claimed calls for determining prescriptive drug abuse, and the generation of electronic patterns indicative of such drug abuse.
In addition, Applicant argues that Borsand, Munoz, Rice, and Edelson also fail to disclose the generation of electronic patterns to indicate prescription drug abuse and they have no teaching of generating an electronic flag to indicate prescription drug abuse.

(A) As per the first argument, the Examiner respectfully submits that the Cunningham reference was the one relied upon to teach "generating from said prescriptive history of said selected purchaser one or more electronic patterns which flag prescriptive drug abuse." Cunningham discloses that "in order to help combat prescription *fraud*, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs...." (see col. 2, lines 55-59 of Cunningham). In addition, Cunningham's initialization process (see Fig. 5) and tracking of refills is a way of determining prescription abuse. Cunningham teaches that a "patient is precluded from securing additional refills without a new prescription" (see col. 3, lines 53-67 of Cunningham). Cunningham also teaches that "a wide variety of reports can be generated from the database" and that the

database will possess a full record of all transactions (see col. 11, line 66 – col. 12, line 21).

Furthermore, the Examiner gave each term the broadest reasonable interpretation in light of the Applicant's specification. The Examiner referred to the specification, but was unable to find any definitions of "abuse" and "patterns" given with precision, clarity, and deliberateness to warrant the meanings currently argued by Applicant. Moreover, words of the claim are generally given their ordinary and customary meaning, unless it appears from the written description that they were used differently by the Applicant. Where an Applicant chooses to be his or her own lexicographer and defines terms with special meanings, he or she must set out the special definition explicitly and with "reasonable clarity, deliberateness, and precision" in the disclosure to give one of ordinary skill in the art notice of the change. See *Teleflex Inc. v. Ficosa North America Corp.,* 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.,* 273 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP § 2111.01. Pursuant to 35 USC § 112, 2nd paragraph "[i]t is Appellant's burden to precisely define the invention, and not the [examiner's]." *In re Morris,* 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). Therefore, it would **not** be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the Applicant in the written description.

For example, regarding "abuse," Applicant merely recites that "All of these entities can have immediate access to potential medication abuse by identification of

needless prescription duplications, potential drug interactions, and multi-source interstate prescriptive medication abuse" (page 24, lines 1-3 of Applicant's specification). As for the term "patterns," the specification is devoid of an explanation. For these reasons, Applicant's claims were given their broadest reasonable interpretation consistent with the specification, and the Examiner applied prior art accordingly.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
ln
2/19/09

/Gerald J. O'Connor/
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